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TITLE: Dynamic Functional Mammoscopy: A Non-Ionizing Imaging

Technique Enhancing Early Detection of Breast Cancer

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	of equivocal mammograph	*		

The imaging technology of Dynamic Functional Optical Mammoscopy (DFOM) has been used to scan patients scheduled for biopsy of breast lesions. These patients were scheduled for core or excisional breast biopsy on the basis of equivocal mammographic and ancillary clinical findings within ACR BI-RADSTM categories 3 or 4. Analysis of test results of 47 patients shows that the DFOM detected cancer in nine of the 11 patients in whom biopsies confirmed malignant lesions giving a sensitivity of 82%. DFOM also correctly identified 24 of 36 benign lesions giving a specificity of 67%. In clinical practice, the adjunctive use of DFOM would have decreased the percentage of biopsies that turn out to be benign from 36/47 (77%) to 12/47 (26%). The negative predictive value, the chance that a negative DFOM result truly indicates a benign lesion, was 24/26 (92%).

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Table of Contents

Front Cover	1
Report Documentation Page	2
Introduction	4
Body	4
Key Research Accomplishments	7
Reportable Outcomes	7
Conclusions	8
References	8
Appendices	9

Introduction

The imaging technology of Dynamic Functional Optical Mammoscopy (DFOM) is a breast scan based upon transmission/absorption of infrared light, which measures the dynamic patterns of breast reactivity of various physiological states in response to soft pressure. DFOM produces a functional rather than a morphological image and the dynamic pattern of tissue reactivity after mild compression is charted. Pilot study results suggested that this innovative DFOM imaging technique has the potential to determine which of the mammographically and clinically indeterminate lesions are benign vs. carcinoma and distinguish those lesions thereby avoiding biopsy. The purpose of the study reported here is to extend the preliminary results of the pilot study at Columbia Presbyterian Medical Center, using DFOM between mammography and biopsy to further evaluate the efficacy of DFOM in evaluation of breast lesions, using biopsy results to confirm diagnosis.

Body

A total of 117 patients scheduled for biopsy were scanned with the identical protocol between June 1, 2000 and September 30, 2000. The study was performed on women scheduled for core or excisional breast biopsy on the basis of equivocal mammographic and ancillary clinical findings within ACR BI-RADSTM categories 3 or 4. Women who met the selection criteria were enrolled from the normal caseload from both screening and diagnostic mammography. Each woman signed an informed consent prior to being scanned.

The scan procedure required approximately 5 minutes. During examination, the breast was placed in the soft breast holder of the system. The breast was then softly compressed by a thin transparent silicone rubber membrane using an applied pressure of approximately 10 mm Hg. For each scan, the breast was symmetrically centered on the illuminator. When the breast was correctly positioned, illumination adjustment and image recording took place following the requirements of the pressure profile.

Optical illumination was provided by an array of red light emitting diodes (LEDs) attached to the bottom surface of the soft breast holder. Light transmitted through the breast was recorded as a temporal sequence for approximately 30 seconds by a highly sensitive digital CCD camera. The image sequences were accumulated in digital memory and processed by proprietary software to accentuate differences in the temporal variations of intensity between normal/benign and malignant tissue.

Each woman was scanned by a trained technologist prior to biopsy. The scans were read by an experienced reader trained in interpreting the scans. Results were reported as either a recommendation for biopsy or a recommendation that the woman be sent to interval follow-up.

Recommendations on the basis of DOFM were compared to pathology reports of malignant or benign which were used as the gold standard. Sensitivity, specificity, and negative predictive value were calculated.

Table 1 gives the patient accounting for the 117 patients reported on during this period.

TABLE 1 - Patients Scanned June 1 - September 30, 2000

Excluded patients*	= 40
Unacceptable scans**	= 20
Scans to be interpreted	= 10
Interpreted scans	= 47
_	
Total scans performed	= 117

^{*}Patients who did into meet the selection criteria for the development study protocol.

Table 2 presents the reasons for scans determined to be unacceptable.

TABLE 2 – Unacceptable Scans	
Lesion sub areolar or located where it cannot be properly illuminated	= 5
Inadequate illumination in area of pathology	= 6
Device related	= 4
Incorrect illumination	= 2
Not enough breast tissue in holder	= 2
Excessive patient movement	= 1
Total	= 20

Below, Table 3 lists reasons for excluding from our study selected patients.

^{**}Patients whose scans were not acceptable to be interpreted.

TABLE 3 – Excluded Patients	
Lesion sub areolar or located where it cannot be properly illuminated	= 12
Previous surgery in ipsilateral breast	= 9
BI-RADs 5 lesion	= 4
Post-menopausal with palpable lesoin	= 3
Relevant record(s) not available oat site of review	= 2
Small breast that could not be properly positioned	= 2
Patient could not remain still	= 1
Biopsy of ipsilateral breast within 3 months	= 1
Biopsy to be performed at another facility	= 1
Not recorded	= 5
Total	= 40

Table 4 presents patient demographics of race and age.

TABLE 4 - Patient Demographics

Race	
White	= 58
African American	= 5
Hispanic White	= 34
Hispanic Black	= 16
Asian	= 2
Other	= 2
Total	= 117

AGE: Average = 56Range = 35-82

Table 5 presents the results of scan interpretation.

TABLE 5 – Results of 47 Patients Scheduled for Biopsy

		Pa	athology	
		Malignant	Benign	Total
DEOM	Biopsy	9	12	21
DFOM	Interval Follow-Up	2	24	26
Recommendation	Total	11	36	47

Sensitivity: 9/11 (82%) Specificity: 24/36 (67%)

Negative Predictive Value (NPV): 24/26 (92%)

The analysis of test results on the 47 patients with interpreted scans shows that the DFOM detected cancer in 9 of the 11 patients in whom biopsies confirmed malignant lesions ("true positives"). This results in a sensitivity of 82%. The system also correctly identified 24 of 36 benign lesions ("true negatives"). In other words, the specificity of the DFOM is 24/36 (67%).

Key Research Accomplishments

Below we summarize our accomplishments in the context of the original Statement of Work, as described in the proposal.

TASK 1. Develop substructure for implementing study (months 1-3).

- (a) Obtained Institutional Review Board (IRB) Approval, including patient consent form.
- (b) Trained three consecutive research associates in protocol and procedures: Patricia Ogiliva 11/30/98 6/3/99, Homyra Hadavand 6/14/99 11/30/99 and Behnaz Mesbah 12/13/99 8/31/01.
- (c) Develop database program to enable data entry and to allow compilation of results.

TASK 2. Develop a database of DFOM dynamic imges and signatures of various pathologic lesions (months 3-34).

- (a) Recruited patients undergoing evaluation of lesions to have DFOM scan prior to tissue sampling or biopsy.
- (b) Correlated DFOM information evaluated for acquired dynamic images and signature types with pathologic lesion by type, grade (Bi-Rads scale) and size. Compared appearance with parenchymal density.

TASK 4. Interim analyses (months 12-26).

(a) Interim analysis has been presented in this report for the fist phase of the study, and is currently being collected for analysis in the next annual report.

Reportable Outcomes

The effectiveness of the DFOM in discriminating between benign and malignant breast lesions has been further evaluated and the preliminary results have been corroborated.

Conclusions

While the number of patients reported on is small, the indications of effectiveness are very encouraging. The results reported above indicate that the adjunctive use of the DOFM in clinical practice would have decreased the percentage of biopsies that turn out to be benign from 36/47 (77%) to 12/47 (26%). The negative predictive value, the chance that a negative DFOM result truly indicates a benign lesion, is 24/26 (92%).

Thus, we are encouraged by these early findings. We will continue to accrue patients and analysis data during the next phase.

References

None.

Appendices

Summary Tables of Scanned Patients - First Year of Study

DOBI Preliminary Results

3
G1 NO - WP
LS6-RS4 NO - NC
t compil NO
G1 NO - WP
G1 YES
NO - WP
LS1-RS1 PENDING
S4 YES
G1 YES
LS2-RS2 PENDING
YES
EUG NO-EUG
G1 NO - WP
EUG NO - EUG
G1 YES
EUG NO-EUG
G1 YES
G
S3 YES
EUG NO-EUG
EUG NO-EUG
G1 YES
EUG NO - EUG
S2 YES
Se NO-WP
EUG NO-EUG
EUG3 NO-EUG
E1 NO - WP,WI
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DOBI Preliminary Results

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19990303A-R - E-KAS	84		8408		YES	INDET	FP	4A		ADH+FC(prolif)+microc	ý
19990212A-R - Park	82	19990303B-L - E-SIL	8408		YES	NL	NL	3	NL	Duct dilation with microcal.	y
1999/03/12-R.AR.PEN PENDING TN TN 3.4 TN FC+FF+microcal 1999/03/12-R.AR.PEN B408 G1 YES TN TN TN AA - 4B TN RS, SA, FA TN F9+FF-C+AD+DH 1999/03/12-R.AR.PEN B408 G1 YES TN TN AA - 4B TN RS, SA, FA TN TN CD TN TN TN TN TN TN TN T	88	19990309A-R - E-KAS	8408		YES	NL	NL	4A	TN	FA	y
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199900136AR NAMICA SALON	88	19990312B-R - A-PEG	8408		YES	N	N		NL	FC+FF+microcal.	ý
19990202BR - MAMCG 6408 G1 YES TN 4A - 4B TN RS, SA, FA 1999022BR - LLES 6408 S3 YES TN TN TN CD 1999022BAR - LLES 6408 S3 YES TN TN CD	89	19990316A-R - M-BRU	8408		YES	FP	FP	က	FP	FF+FC+AD+DH	۸
19990022AR P.L.LES 900 FENDING TN TN CD 19990022AR P.L.LES 840B YES TN TN TN CD 19990022AR P.L.LES 840B YES TN NDET CP CD 1999022AR P.L.LES 840B YES NDET NDET CP CP 1999022AR P.L.CDAV 840B 80C YES NDET NDET CP CP NDET 199902AGAR P.A.FRA 840B G1 YES NDET AN NDET CP FF	90	19990316B-R - M-MCG	8408		YES	N	N	1 1	N	RS, SA, FA	λ
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19990413A PENDING	108	19990412B			PENDING						
19990416A - K-ATH 8408 PENDING	109				PENDING						
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19990421A-L - M-DIA 8408 S5 YES TN PR TN PR 4A FP SA+microc. 19990421B-R - S-COR 8408 G1 YES TN TN AA TN FC+FA+SA FC 19990422B-L - E-WEI 8408 S3 YES TN TN TN FA 19990422B-L - R-RIC 8408 S3 YES TN FA TN FA 19990426A B408 S3 YES NS FN S DCIS+ID P 19990427A-R - A-AAR 8408 S3 YES NS FN S DCIS+ID P Patient ID Protocol Press. P Acceptable Blind Adjunct BiRads Unblind Biopsy S 19990427B-R - NO-UTT 8408 G1 YES TN FA+FC+LS+microcal S 19990428A B FN A TN FA+FC+LS+microcal S	111	19990419A			PENDING						
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19990422B-L - R-RIC 8408 S3 YES TN TN FA TN FA FA<	114		8408	G1	YES	Z.	N.	4A	NT	Z	
19990426A PENDING	115	19990422B-L -	8408	S3	YES	N	Z	SN	N	FA	⊁
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DOBI Preliminary Results

121	19990428B			PENDING						
122	19990503A			PENDING						
	19990504A			PENDING						
	19990506A			PENDING						
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140	19990520B			PENDING						
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	19990525A-L - I-REY	8408	S2	YES	NL	TN	3	TN FA	FA	
_	19990527A-R	8408		YES		NL				
_	19990527B-L	8408		NO-MV						
145	19990527C-R	8408		NO-MV						
146	19990601A			PENDING						
147	19990602A			PENDING						
	19990603A			PENDING						
$\overline{}$				PENDING						
150	19990603C - VOL			PENDING						
				N						
_	19990615B-L - D-MES	8408	G1	YES	N	NL	4A	NL	TN Intraductal papilloma	
_	19990616A-R - M-TAV	8408		YES	4NFP	A EP	3	FP	FP FC+microcal	
154	19990616B-L - M-IZS	8408	G1	YES	dТ	ТР	4B	TP	TP DC+ID	
155	19990617A									
	19990621A									
	19990621B									
158	19990621C									
СР	_	Protocol	Press. P	Acceptable	Blind	Adjunct	BiRads	Unblind	Biopsy	S. conf
159	_	8408		YES	NL	NT	4A	NL		
160	19990623B-R - NO-BUC	8408	G1	YES	ЬP	FP	4A	FP FC	FC	
161	19990625A			NO-VOLUNT						

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NO-VOLUNT									
162 19990625B									
162	00	163	164	165	166	167			

			COLUMBIA			
Ω	EXCLUDED ACCEPT	ACCEPT	PATHOLOGY	AGE	RACE	INTERPRETATION
	ي	June-00				
06-01A	11		99 Benign	61	MH	
06-01C	11	0,	99 Benign	35	면	
06-05A	0		0 Benign	61	МH	N_
06-05B	0	.,	26 Benign	99	MΗ	
06-07A	0		0 Benign	7.1	3	N.
06-07B	11		99 Benign	35	里	
06-07C	26		99 NK		₹	
06-08A	8	5,	99 Benign	52	>	
06-08B	0		0 Benign	50	ŊI N	N.
06-08C	0	.,	27 Benign	64	3	
O80-90	0		30 Benign		3	
96-08E	0		26 Malignant		× H	
06-12A	0		0 Benign	49	3	NH
06-12B	0		0 Benign	56	MH.	N.
06-13A L	0		0 Benign	40	ΑH	N.F.
06-13B R			0 Benign	40	ΑH	Z.
06-14B	0		0 Benign	63	MH	FP
06-15A	26	6	99 NK		모	
06-19A	2		99 Benign	39	МH	
06-20A					AA	
06-21A	0		0 Malignant	44	MH	ТР
06-22A	0		0 Benign	82	>	Z
06-22B	0		0 Benign	48	무	FP
06-27A	0	2	26 Benign	64	8	
06-27B					ΑM	
06-28A	0		0 Benign	52	MΗ	FP
06-29A	9		99 Malignant		3	
06-29B	0		0 Benign	20	HW	TN
JUNE TOTALS	TALS:					
TOTAL SCANS:	ANS:					
ACCEPTABLES	3LES	(12 benign/1 malignant)	alignant)			
UNACCEPTABLES	TABLES					
EXCLUDED PTS) PTS					
181						

12/19/00

	July-00						
07-03A	9	1 66	99 Benign	46	>		
07-05A	22	99 NK	ξ		3		
07-05B	19	99 NK	¥	89	里		
07-05C	0	17 [17 Benign	59	8		
07-06A L	0	0	0 Benign	65	¥	F	
07-06A R	0	0	0 Benign	65	MΗ	NL	
07-11A	0	17 [17 Benign	37	>	A CONTRACTOR OF THE CONTRACTOR	
07-11B	11	1 66	99 Benign	57	>		
07-13A	0	21 1	21 Malignant	54	3		
07-13C	11	1 66	99 Benign	38	OTHER		
07-17A	12	99 NK	¥		3		
07-17B	1	99	99 Benign	43	×Η		
07-17C	0	111	11 Malignant	46	里		
07-18A L	0 10,11	3	Benign	49	8		
07-18B R	0 10,11		Benign	49	3		
07-24A	0	11	11 Benign	38	8		
07-24B				61	8		
07-26A	0	111	11 Benign	73	OTHER		
07-27B	9	166	99 Malignant	81	AA.		
07-28A	0	0	0 Benign	22	>	N.	
07-31A	9	1 66	99 Malignant	99	3		
JULY TOTALS:							
TOTAL SCANS:							
ACCEPTABLES	3 benign	-					
UNACCEPTABLES							
EXCLUDED PTS	_						
TBI							

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12/19/00

08-01A 11 99l Malignant 64 W 08-01C 11 99l Malignant 64 W 08-01C 0 0 0 0 0 08-01C 0 0 0 0 0 0 08-02B 0		August-00					
11 99 NK 51 W 0 0 Benign 63 W 0 0 0 Benign 44 HB 0 0 0 Benign 55 W 0 0 Benign 60 W 0 0 Benign 60 W 0 0 Benign 60 W 0 0 Benign 61 HW 0 0 0 0 0 0 0 0 0	08-01A	-	66	Malignant	64	≥	
Color Colo	08-01C	=	66	¥	51	^	
O Benign 69 HW O	08-01D	0	0	Benign	53	>	FP
Colored Colo	08-02A	0	0	Benign	69	MΗ	N.
1 0 0 0 0 0 0 0 0 0	08-02B	0	0	Malignant	46	>	TP
0 21 Benign 36 W 1 99 Malignant 76 W 0 0 Benign 55 W 1 0 13 Benign 55 W 1 0 0 Benign 68 W 1 0 0 Benign 69 W 1 0 0 Benign 60 W 1 0 0 Benign 61 W 1 0 0 0 Benign 61 W 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0 0 0 0 1 0 0 0	08-02C	0	0	Benign	44	里	FP
1 99 Benign 36 W 1 99 Malignant 76 W 0 0 0 0 0 13 Benign 55 W 0 0 0 0 0 14 99 Benign 55 W 0 0 0 0 0 14 99 Benign 55 W 0 0 0 0 0 0 0 0 0	08-04A	0	21	Benign	40	모	
1 99 Malignant 76 W 0 0 0 0 1 1 99 Malignant 54 HW 0 0 13 Benign 55 W 0 0 0 Benign 55 W 1 0 0 Benign 63 W 1 0 0 Benign 64 HW 0 0 0 Benign 65 HW 0 0 0 0 0 Benign 65 HW 0 0 0 0 0 0 0 0 0	08-09A	26	66	Benign	36	>	
Name	08-09B	-	66	Malignant	92	>	
Color	08-09C	0	0	Benign	54	AH	Z.
Color 13 Benign 55 W W W W W W W W	08-10A	0	0	Malignant	63	>	ТР
R 6 99 Benign 55 W 0 0 0 Benign 48 W 0 0 0 Benign 55 W 11 99 Malignant 68 W 12 99 Benign 61 W 13 99 Benign 63 W 14 99 Malignant 68 HW 15 16 99 Benign 61 HW 16 99 Benign 61 HW 17 99 Benign 61 HW 18 99 Benign 61 HW 19 99 Benign 61 HW 11 99 Benign 61 HW 12 99 Benign 61 HW 13 99 Benign 61 HW 14 99 Benign 61 HW 15 99 Benign 61 HW 16 99 Malignant 62 HW 17 17 99 Benign 47 W 18 99 Benign 47 W 19 99 Benign 47 W 10 10 10 10 10 11 99 Benign 47 W 12 99 Benign 47 W 14 99 Benign 47 W 15 17 17 18 16 18 18 18 17 18 18 18 18 18 18 18 18	08-10B L	0	13	Benign	55	≥	
0	08-10C R	9	66	Benign	55	>	
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11 99 Benign 50 AA 11 99 Benign 55 W 1 99 Benign 63 W 10 99 Atypia 49 ASIAN 10 99 Atypia 49 ASIAN 11 99 Benign 60 W 12 89 Benign 61 HW 13 99 Benign 61 HW 0 0 Benign 62 HB 0 0 Benign 63 HW 0 0 Benign 64 HW 0 0 0 0 Benign 64 HW 0 0 0 0 0 0 0 0 0	08-14B					뮈	
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11 99 Benign 36 HB 1 99 Malignant 63 W 0 0 Malignant 68 W 10 99 Atypia 49 ASIAN 10 99 Atypia 49 HW 11 99 Benign 60 W 11 99 Benign 60 W 0 0 Benign 61 HW 0 0 Benign 740 HW 0 21 Benign 40 HW 0 0 0 HW 0 0 0	08-15B	0	0	Benign	55	3	FP
1 99 Malignant 63 W 0 0 Malignant 68 W 10 99 Atypia 49 ASIAN 11 99 Benign 60 W 11 99 Benign 60 W 11 99 Benign 61 HW 0 0 0 0 0 11 99 Benign 61 HW 0 0 0 0 0 11 99 Benign 61 HW 0 0 0 0 0 11 99 Benign 40 HW 0 0 0 0 0 11 99 Benign 40 HW 0 21 Benign 40 HW 0 21 Benign 40 HW 0 21 Benign 47 W 11 99 Benign 47 W 12 ABLES (124) BENIS 13 14 99 Benign 47 W 14 99 Benign 47 W 15 TOTALS: 124 124 16 124 124 124 17 124 124 124 18 124 124 124 19 124 124 124 124 10 124 124 124 124 11 12 124 124 124 124 12 124 124 124 124 124 13 124 124 124 124 124 124 124 14 12 12 124	08-16A	=======================================	66	Benign	36	모	
0 Malignant 68 W 0 Benign 48 HW 0 D Benign 48 HW 0 D Benign 60 W 0 D Benign 60 W 0 D Benign 60 W 0 D Benign 61 HW 0 D Benign 74 HW 0 D Malignant 54 HW 0 D Malignant 54 HW 0 D Malignant 54 HW 0 D Malignant 61	08-17A	-	66	Malignant	63	>	
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10 99 Atypia 49 ASIAN 0 21 Benign 60 W 1 99 Malignant 68 HW 1 99 Benign 61 HW 0 0 Malignant 54 HW 0 21 Benign 42 HW 0 21 Benign 47 W 0 21 W 0 0 W 0 0 W 0 0 W 0 0 W 0 0 W 0 0 W	08-21A	C	C	Benian	48	¥	Z
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0	08-21C		3	2016	2	3	
0 21 Benign 60 W 1 99 Malignant 68 HW 1 99 Benign 51 W 0 0 Benign 43 HW 0 0 Benign 49 HW 0 0 Benign 51 HW 0 0 Benign 51 W 1 99 Benign 40 HW 0 21 Benign 42 HW 1 99 Benign 42 HW 0 21 Benign 47 W 1 99 Benign 47 W 1 90 Benign	08-21D				80	E	
11 99 Malignant 68 HW 11 99 Benign 69 W 0 0 Benign 43 W 0 0 Benign 49 HW 0 0 Benign 41 HW 0 0 Benign 40 HW 0 0 Malignant 54 HW 0 21 Benign 42 HW 0 21 Benign 42 HW 0 21 Benign 47 W 11 99 Benign 47 W 124 99 Benign 47 W 14 99 Benign 47 W 15 TOTALS:	08-21E	C	21	Benian	90	3	
11 99 Benign 69 W 10 10 10 10 10 10 10	08-230		00	Malianant	89	NI I	
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3 99 Benign 51 W 0 0 Benign 43 W 0 0 0 Benign 49 HW 0 0 0 Benign 61 HW 0 0 0 Benign 40 HW 0 0 Malignant 82 HB 0 0 Malignant 54 HW 0 21 Benign 42 HW 0 21 Benign 47 W 11 99 Benign 42 HW 0 21 Benign 47 W 12 CANS: CANS	U0-20A	=	88	penign	Ro	>	
O Benign 43 W O Benign 49 HW O Benign 61 HW O Malignant 82 HB O Malignant 82 HB O O Malignant 54 HW O 21 Benign 42 HW O 21 Benign 45 HW O 21 Benign 47 HW O 31 Benign 47 HW O 4 99 Benign 47 HW O 5 1 Benign 47 HW O 6 1 1	08-29A		66	Benign [51	>	
0 0 Benign 49 HW 0 0 Benign 61 HW 0 0 Benign 61 HW 0 0 Benign 51 W 0 0 Benign 40 HW 0 0 Malignant 82 HB HW 0 0 Malignant 84 HW 0 21 Benign 42 HW 0 21 Benign 42 HW 0 21 Benign 47 W 0 21 Benign 47 W 0 21 Benign 47 HW 0 39 Benign 47 HW 0 3	08-29B	0	0	Benign	43	≯	N
0 0 Benign 61 HW 0 0 Benign 51 W 0 0 Benign 51 W 0 0 Benign 40 HW 0 0 Malignant 82 HB HW 0 0 0 Malignant 54 HW 0 21 Benign 42 HW 0 21 Benign 47 HW	08-29C	0	0	Benign	49	ΝH	N
0 0 Benign 51 W 2 99 Benign 40 HW 0 0 Malignant 82 HB 11 99 Benign 40 HW 6 99 Malignant 54 HW 0 21 Benign 42 HW 11 70TALS: ABLES (12/4)	08-31A	0	0	Benign	61	×Η	N.
2 99 Benign 40 HW 0 0 Malignant 82 HB 11 99 Benign 40 HW 0 21 Benign 42 HW 11 99 Benign 42 HW 11 99 Benign 47 W 11 10 14 15 15 12 15 15 15 13 15 15 14 15 15 15 15 15 16 15 15 17 17 17 17 17 17 18 18 18 19 18 19 10 19 19 11 12 15 12 15 15 13 15 15 14 15 15 15 15 16 15 17 17 18 18 19 19 10 15 11 10 12 15 13 15 14 15 15 15 16 15 17 15 18 15 19 15 10 15 10 15 11 15 12 15 13 15 14 15 15 15 15 15 16 15 17 15 18 15 18 18 19 18 10 18 10 18 10 18 11 18 12 18 13 18 14 18 15 18 15 18 16 18 17 18 18 18 18 18 19 18 10 18 10 18 10 18 10 18 10 18 11 18 12 18 13 18 14 18 15 18 15 18 16 18 17 18 18 18 18 18 18 18	08-31B	0	0	Benign	51	>	N
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11 99 Benign 40 6 99 Malignant 54 0 21 Benign 42 1 99 Benign 47 1 99 Benign 47 1 TOTALS: 47 1 99 Benign 47 1 ABLES (124)	08-31D	0	0	Malignant	82	모	TP
6 99 Malignant 54 0 21 Benign 42 4 99 Benign 47 S: (12/4)	08-31E	17	66	Benign	40	× H	
0 21 Benign 42 4 99 Benign 47 .S: (12/4)	08-31F	9	66	Malignant	54	Ž	
4 99 Benign 47 -S: (12/4)	08-31G	0	21	Benign	42	¥	
ij	08-31H	4	66	Benign	47	×	
ij							
	AUGUST TOTALS:						
	TOTAL SCANS:						
UNACCEPTABLES FYCHINEN DTS	ACCEPTABLES	(12/4)					
EYCI IIDED DTS	UNACCEPTABLES						
TYPEPOLICE				-			

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09-05A	4	99 Ma	99 Malignant	80	۸	TN
09-05B	0	0 Benign	nigu	52	8	TN
09-05C	0	0 Benign	nign	9	>	
09-05D	7	3N 66		45	里	
09-06A	9	99 Benign	nigu	79	3	
09-06B	0	0 Benign	nign	43	Α	FP
09-07A	0	o Ma	0 Malignant	74	МН	ТР
09-07B	0	21 Benign	nign	69	¥	
09-11A	0	0 Benign	nign	54	ASIAN	N
09-11B	0	0 Ma	0 Malignant	89	ΑH	TP
09-11C	0	0 Be	Benign	20	>	N
09-13A					MΗ	
09-13B					MΗ	
09-14A	0	0 Ma	0 Malignant	48	3	TP
09-14B	0	21 Ma	21 Malignant	50	3	
09-14C	7	99 Benign	njan		>	
09-14E	0	0 Benign	nign	46	≥	FP
09-14F(8)	4	99 Benign	nign	42	모	
09-18A	0	0 Ma	0 Malignant	80	3	NH
09-18B	0	0 Benign	nign	42	모	FP
09-19A	9	99 Ma	99 Malignant	74	>	
09-19B					¥	
09-20A	0	o Ma	0 Malignant	29	≥	TP
09-20B					8	
09-20C	0	o Ma	0 Malignant	75	>	FN
09-21A	0	0 Benign	nign	63	모	FP
09-21B	0	16 Benign	nign	51	3	
09-25A	11	99 Benign	nigu	45	Λ	
09-28A	11	99 Benign	nign	56	>	
09-28B	0	0 Be	Benign	57	MH	FP
SEPTEMBER TOTALS:	ALS:					
TOTAL SCANS:						
ACCEPTABLES	6)	(9/6)				
UNACCEPTABLES						
EXCLUDED PTS						
TBI						
OVERALL TOTALS	S					
TOTAL SCANS:		117				
ACCEPTABLES	4	47(36 benign/11 malignant)	lignant)			
UNACCEPTABLES		20				
EXCLUDED PTS		40				
TRI		10				

PATIENT SCREENING EXCLUSION CODES

CL	IN	ICA	L

- 01 Outside of BI-RADS categories 3 and 4
- 02 Not all records available at site for review
- 03 Biopsy at another facility
- 04 Post-menopausal with a palpable lesion
- 05 Pregnant or lactating
- 06 Breast surgery in ipsilateral breast
- 07 Biopsy of ipsilateral breast (core or excisional) within past three months
- 08 Surgical clips or scarring in or on ipsilateral breast
- 09 Patient refused consent.

IMAGING

- 10 Small breasts that, in the judgment of the technologist, cannot be properly positioned
- Lesion is subareolar or located where it cannot be properly illuminated (e.g. lesions visible on MLO view that *cannot also* be visualized on the CC view)
- 12 Patient unable to stand still

CODES FOR UNACCEPTABLE SCANS

BREAST POSITIONING:

- 13 Breast too small
- 14 Soft holder not closed properly
- 15 Non-symmetrical positioning
- 16 Not enough breast tissue in holder

ILLUMINATION

- 17 Size of illumination too small
- 18 Size of illumination too large
- 19 Intensity too high
- 20 Intensity too low
- 21 Inadequate illumination in area of pathology
- 22 Ambient light leakage

DEVICE RELATED

- 23 Computer error
- 24 Air leakage
- 25 Other error: Copy error message number from screen
- 26 Other Device Related: Describe

PATIENT RELATED

- 27 Excessive patient movement
- 28 Patient complaint/refusal after scan has started
- 29 Other Patient Related: Describe

OTHER

30 Other: Describe

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C:\Mv Documents\CRFs\COMBO exclusion CODES.doc (EMP)